

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Atty. Michael W. Krenicky on January 26, 2011.

2. The application has been amended as follows:

2.1. In claim 19:

- a) line 1, the phrase "the pH of" has been deleted;
- b) line 2, "is" has been replaced with --has a pH of--.

2.2. In claim 20:

- a) line 1, the phrase "the pK<sub>a</sub> of" has been deleted;
- b) line 2, "is" has been replaced with -- has a pK<sub>a</sub> in the range of--.

2.3. In claim 26, line 1, "A" before "granule" has been replaced with --The--.

2.4. In claim 30:

- a) line 3, "30%" has been replaced with --25%--

(support is found on page 5, line 29 and page 6, line 21);

- b) line 9 (last line), after "component", the following has been added:

--and wherein the amount of acidic buffer component present in the core is more than 20% of the total amount of acidic buffer component present in the granule--

(support is found in original claim 22).

2.5. In claim 33:

- a) line 1, "A" before "granule" has been replaced with --The--.
- b) line 1, the phrase "the pH of" has been deleted;
- c) line 2, "is" has been replaced with --has a pH of--.

2.6. In claim 34:

- a) line 1, "A" before "granule" has been replaced with --The--.
- b) lines 1-2, the phrase "the pK<sub>a</sub> of" has been deleted;
- c) line 2, "is" has been replaced with -- has a pK<sub>a</sub> in the range of--.

2.7. Claim 35 has been cancelled.

### **STATEMENT OF REASONS FOR ALLOWANCE**

3. The following is an examiner's statement of reasons for allowance:

The claims in their present amended forms have overcome the 35 USC 112, first paragraph rejection and the obviousness rejection based upon Green in view of Mimura, the close prior art of record, because even though Green in view of Mimura teaches a core comprising the recited acidic buffer components, the combination of reference fails to teach, disclose or suggest a coated granule or the process for preparing said granule wherein the coating comprises the recited acidic buffer components and their recited amounts. Accordingly, the subject matter, as a whole, would not have been obvious to one of ordinary skill in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lorna M. Douyon whose telephone number is 571-272-1313. The examiner can normally be reached on Mondays-Fridays 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorna M Douyon/  
Primary Examiner, Art Unit 1761

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